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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,223	12/05/2001	Xiaorong He	C-3409/1/US	4333

26648 7590 01/17/2007
PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
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EXAMINER	
CHONG, YONG SOO	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/008,223	HE, XIAORONG	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,20,21,23-37 and 39-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18, 20-21, 23-37, 39-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 11/15/2006. Claim(s) 18, 20-21, 23-37, 39-53 are pending and examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and repeated below for Applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18, 20-21, 23-37, 39-53 are rejected under 35 U.S.C. 103(a) as being obvious over Bolt et al. (EP 396,335) in view of Harrison et al. (US Patent 6,086,909).

The instant claims are directed to a pharmaceutical composition containing celecoxib and a dispersion-enhancing amount of an effervescent agent, wherein the dosage form is adapted for swallowing without prior disintegration in water or in the mouth.

Bolt et al. teach a tablet comprising a medicament and an effervescent couple (pg. 7, line 32), where the medicament is selected from non-steroidal anti-inflammatory drugs (pg. 2, lines 40-44). Citric acid and calcium carbonate are specified (pg. 3, lines 3-5). The ratio of acid to base is disclosed to be 4:3 to 1:3 (pg. 3, lines 7-10). A 250 mg. tablet is specified with acid (0.5-20%) and base (0.5-30%) content (pg. 3, lines 17-20). Bolt et al. also disclose that solid dosage forms, which are swallowed, such as tablets and capsules, provide accurate dosage and avoid taste problems (pg. 2, lines 9-10).

However, Bolt et al. fail to disclose the specific non-steroidal anti-inflammatory drug, celecoxib, nor a dosage form adapted for swallowing without prior disintegration in water or in the mouth.

Harrison et al. teach that celecoxib is a non-steroidal anti-inflammatory drug (col. 7, lines 40-42).

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to use celecoxib as the non-steroidal anti-inflammatory drug in the composition that is taught by Bolt et al. for swallowing without prior disintegration in water or in the mouth.

A person of ordinary skill in the art would have been motivated to include celecoxib because: (1) Bolt et al. teach oral administration of a composition comprising a non-steroidal anti-inflammatory drug; (2) Bolt et al. teach that solid dosage forms, which are swallowed, such as tablets and capsules, provide accurate dosage and avoid taste problems; and (3) Harrison et al. teach that celecoxib is a non-steroidal anti-inflammatory drug. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in producing an effective pharmaceutical composition comprising celecoxib that provides accurate dosage and avoids taste problems.

Response to Arguments

Applicant argues that Bolt et al. teach away from dosage forms adapted for swallowing without prior disintegration in water or in the mouth because Bolt et al. disclose chewable tablets.

This is not persuasive because the limitation "chewable" is given little patentable weight since it does not materially change the physical composition disclosed by Bolt et al. Furthermore, since taste problems are associated with chewable tablets, it is obvious to one of ordinary skill in the art to have swallowed the tablet. Examiner views that the chewable tablets disclosed by Bolt et al. can be either swallowed or chewed before swallowing, which does not necessarily involve disintegration in the mouth.

Examiner respectfully reminds the Applicant that the limitation "adapted for swallowing with prior disintegration in water or in the mouth" will be given little

patentable weight when all of the components of the instant invention are disclosed. Examiner then asks how this property is not present in the composition disclosed by Bolt et al. or how this property is only present in the instant invention.

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER